UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OREXO AB, Plaintiff, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. 3:11–cv–3788–FLW–LHG Hon. Freda L. Wolfson, U.S.D.J. Hon. Lois H. Goodman, U.S.M.J. Document Filed Electronically

EXPERT DECLARATION OF EDMUND J. ELDER, JR., PH.D., R.PH.

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EXPERT DECLARATION OF EDMUND J. ELDER, JR., PH.D., R.PH.

I. BACKGROUND AND QUALIFICATIONS

1. Development of pharmaceutical dosage forms and drug delivery systems, including rapid release dosage forms, has been the focus of my career for the past 27 years. I obtained my Bachelor of Science degree in Pharmacy and Doctor of Philosophy (Ph.D.) degree in Pharmaceutical Sciences from the Medical University of South Carolina in 1985 and 1989, respectively. My *curriculum vitae* including a list of my publications is attached as Exhibit A. I have had extensive experience formulating pharmaceutical products to enhance drug delivery from 1985 to today.

2. I am the Director of the Zeeh Pharmaceutical Experiment Station in the School of Pharmacy at the University of Wisconsin-Madison (UW). The Station works for both academia and pharmaceutical industry clients in developing pharmaceutical dosage forms and providing technical expertise regarding issues arising with pharmaceutical dosage form development and manufacture. As Director, I am responsible for providing pharmaceutical pre-formulation and formulation expertise to support pharmaceutical and biopharmaceutical development collaborations across the UW System campuses and for clients outside the university. I actively participate in educational programs sponsored by the Station and the UW School of Pharmacy in which I teach pharmaceutical industry scientists and others in related fields about the process and science of drug development.

3. My work at the Station focuses on the development and improvement of pharmaceutical dosage forms. I have worked with various tablet dosage forms while at the Station, including rapid release formulations. I also have worked with conventional solid dosage forms, including tablets and capsules, and with injectable solutions and suspensions, dosage forms for application to the skin and inhalable dosage forms.

4. Prior to my employment at the University of Wisconsin-Madison, I was the Global Pharmaceutical Development Director at Dowpharma, a business unit of The Dow Chemical Company that was dedicated to serving the pharmaceutical and biopharmaceutical

industries. In this role, I was responsible for overseeing and directing all technical aspects of the drug development business for nanotechnology applications, including the formulation and development of nanoparticles into solid dosage forms, such as tablets and capsules. I led numerous technology development collaborations and alliances between Dow and other companies, utilizing nanotechnology to achieve enhanced drug delivery.

5. Prior to my employment at Dowpharma, I was Senior Group Leader for formulation and process development at Glaxo Wellcome Inc. (now GlaxoSmithKline, Inc.) where I oversaw and directed the work of ten formulation and process development scientists. I began my industrial career as a Senior Scientist, Research Investigator, and then Research Leader at the predecessor company, Glaxo Inc.

6. In these various roles of increasing responsibility, I gained extensive experience in numerous aspects of pharmaceutical dosage form development and manufacturing including working on numerous enhanced drug delivery systems. I designed and conducted formulation studies, selected excipients for use in dosage forms, assessed whether a desired drug release was obtained from dosage forms and modified the composition of dosage forms to achieve a desired drug release, formulated dosage forms that achieved a desirable mixture of functionality, stability and compatibility and manufactured dosage forms for use in clinical studies.

7. I also served as the primary interface between Glaxo and numerous external development and manufacturing sites that required me to provide pharmaceutical expertise used to develop oral dosage forms including enhanced drug delivery systems and tablets.

8. My project management experience at Glaxo and Glaxo Wellcome included extensive management of both formulation and process development. I represented Glaxo's Chemistry Manufacturing and Controls interests on global product development teams. I led several new product introduction teams, during which time I ensured that newly-developed technology was successfully transferred from research and development facilities to manufacturing facilities and solved the myriad problems that arise when a formulation and associated manufacturing process is moved from one location and one set of equipment and

people to another location and different people. I was the key liaison between the Pharmaceutical Development function at Glaxo and the FDA for numerous pre-approval inspections of manufacturing facilities in both the United States and abroad.

9. Prior to joining Glaxo, I worked in the pharmaceutical field for four years as a Research Pharmacist in the Pharmaceutical Development Center in the Department of Pharmaceutical Sciences at the Medical University of South Carolina, concurrent with my graduate education. My duties involved formulation development and manufacture of dosage forms for drug companies, including an oral dosage form requiring enhanced drug delivery.

10. As of August 2012 I have made 52 scientific presentations on topics including sustained release formulations, formulation development, evaluation and optimization of drug product manufacturing, dissolution testing, and particle engineering in the area of nanotechnology.

11. I have presented lectures and seminars at Schools or Colleges of Pharmacy throughout the United States on topics including an overview of drug development, assessment and optimization of drug manufacturing processes, formulation development, excipient considerations in formulations, scale-up, technology transfer, and applications of particle engineering to nanotechnologies as a result of my participation from 1993-2005 in the Visiting Scientist Program for Schools of Pharmacy and Pharmaceutical Scientists. I have also participated as an instructor by giving over 120 lectures at continuing education Short Courses presented to pharmaceutical industry scientists covering the following subjects: particle engineering and nanotechnology, drug solubilization, stability, drug delivery and dosage form design. I currently serve as a guest lecturer in the Department of Pharmaceutical Sciences at the University of Wisconsin-Madison covering the topics of an introduction to the drug development process and formulation development.

12. I have been a member of the American Association of Pharmaceutical Scientists since 1987. I am also a member of Sigma Xi, The Scientific Research Society and a lifetime member of the National Eagle Scout Association.

13. I am on the Editorial Advisory Boards for the journals *Drug Development and Industrial Pharmacy* and *Journal of Biosimilars and Biowaivers*. I have reviewed journal articles in the pharmaceutical sciences submitted for publication to the *European Journal of Pharmaceutics and Biopharmaceutics*; the *Journal of Biomedical Nanotechnology*; the *International Journal of Pharmaceutics*; *Pharmaceutical Research*; and *Drug Development and Industrial Pharmacy*. I have also screened scientific papers submitted for the annual meetings of the American Association of Pharmaceutical Scientists.

14. A more detailed review of my professional background is provided in my *curriculum vitae*, attached as Exhibit A.

15. A list of my publications is also included in my CV (Exhibit A)

16. A list of my testimony as an expert at trial or by deposition in the last 4 years is provided as Exhibit B

II. MATERIALS REVIEWED

17. I have reviewed the '910 patent as well as its entire prosecution history (ORM_00000009 to ORM_00000249). I have also reviewed European Patent EP 0 324 735 ("Nystrom") and the Revised Joint Claim Construction and Prehearing Statement. I understand that the '910 patent is Exhibit 1 to the Declaration of Constantine Koutsoubas ("Koutsoubas Decl."), the prosecution history is Exhibit 2 to the Koutsoubas Declaration, and the Nystrom reference is Exhibit 3 to the Koutsoubas Declaration. In this declaration, I will cite to the '910 patent as " '910 patent," I will cite to the Nystrom EP 0 324 735 patent as "Nystrom" and I will cite to pages in the '910 patent prosecution history by bates number.

III. BACKGROUND OF UNDERLYING TECHNOLOGY

18. Drug formulation development is a complex process requiring an understanding of the physiochemical properties of the drug and inactive additives (excipients) as well as the physiological features that the dosage form and drug will be exposed to in the body following

administration. Examples of some of the physiochemical properties of the drug that must be considered include solubility, permeability, partitioning and stability. Examples of some of the physiological considerations, in addition to achieving the desired therapeutic effect, include absorption, protein binding, metabolism and toxicity.

19. During development, the formulator will devise a development strategy for the drug based on their understanding of these various factors and also the target product profile, which includes input from marketing on desired attributes of the product that will hopefully eventually be administered to patients. The target product profile includes the desired disease requiring treatment, patient population, indication(s), including efficacy, safety and tolerability objectives, route of administration, dose and dosing regimen, drug product presentation (packaging, storage conditions, stability/shelf life, etc.), markets & market size, cost and price.

20. The primary objective of the drug development process and particularly formulation development is to deliver the right drug in the right dose, at the right time, by the right route, to the right patient, in order to achieve the desired therapeutic effect.

21. A critical evaluation for orally administered products is having an understanding of how solubility and solubilization rate of the drug and dosage form can impact absorption and bioavailability (the amount of drug that gets into the blood stream).

22. In order for drugs to get absorbed through the mucosal barrier of the gastrointestinal tract (GI); which includes the mouth, esophagus, stomach, small and large intestines and rectum; they must first dissolve in the GI fluids. In order for a drug contained in a solid oral dosage form to get absorbed orally, that dosage form must begin to break apart so that the excipients can disintegrate to release the drug, then the drug must dissolve. Once in solution, the drug can be absorbed, assuming it also has adequate stability in the GI fluids and adequate permeability properties to cross the GI epithelium. Once absorbed, the drug is then available in the blood stream for circulation to the site of therapeutic action, unless it is metabolized in the liver immediately following absorption from the small intestines (known as first-pass metabolism).

23. The formulator must also consider the diversity of conditions to which the drug is exposed during transit through the GI tract. For example, significant pH differences, enzymes, bacteria, and volume differences exist at various locations. These are some of the physiological factors that can adversely affect solubility, stability and absorption of the drug.

24. Formulators have a wide range of approaches available for consideration in developing an appropriate dosage for administration to the patient. The most common solid oral dosage forms are tablets and capsules. Examples of release modifications that a formulator could choose to alter the delivery of drug from tablets and capsules include enteric coating for delayed release delivery, sustained release, and enhanced or fast release. A skilled formulator will have a thorough understanding of the properties of the various excipients that can be used to achieve the desired drug release alteration and how these excipients impact the rate of release.

25. A sublingual tablet is a form of fast disintegrating/dissolving tablet which is placed under the tongue to achieve rapid drug absorption into the systemic circulation. This delivery site is commonly used for drugs which exhibit first-pass metabolism and/or require rapid absorption to achieve their maximum therapeutic benefit.

26. Ordered mixing is a method for enhancing drug release which is disclosed in Nystrom. Nystrom describes ordered mixtures as using "adherent particles" of active substance (Nystrom, 1:49-2:12) where "the active substance(s) is (are) distributed uniformly over the surfaces of readily dissolvable carrier particles, therewith enabling the therapeutically active substances to dissolve more quickly. Consequently, the active substances will dissolve more rapidly when administered and consequently act more quickly, in a highly advantageous manner." (Nystrom, 1:30-37).

27. The particles adhere to the carrier particles in the dry mixing process. Also, since the carrier particle described in Nystrom is "readily dissolvable", the use of dry mixing is necessary; otherwise, the carrier has the potential to dissolve during the manufacturing process; thus, reducing the size of the carrier particle and the ratio of carrier particle size to drug particle size. Addition of water could also dissolve the drug or other soluble excipient, which could then

precipitate in an uncontrolled manner during the drying process; thus not being "distributed uniformly over the surfaces of readily dissolvable carrier particles" in an ordered mixture.

IV. OVERVIEW OF THE '910 PATENT

28. I read the '910 patent as being directed toward a person having at least a Bachelor of Science degree in chemistry, pharmacy, engineering, or a related science, or a Doctor of Pharmacy (Pharm.D.) degree, and a minimum of three years of experience in pharmaceutical formulation development. The '910 patent is also directed to a person with a Master of Science degree in Pharmaceutical Sciences or a related scientific field and at least one year of experience in pharmaceutical formulation development. The '910 patent is also directed to a person with Ph.D. in Pharmaceutical Sciences or a related scientific field with experience in pharmaceutical formulation development.

29. In view of my education and experience, I consider myself qualified to offer my opinion as a person to which the '910 patent is directed. I also was qualified as such a person when the '910 patent was filed, which I understand was filed as a Swedish patent application in 1998.

30. The '910 patent claims an essentially water-free ordered mixture pharmaceutical composition that was known in the art as I described above. The claims also require the ordered mixture as described above where (according to both claims 1 and 19) there are "microparticles of at least one pharmaceutically active agent adhered to the surfaces of carrier particles" with "said [carrier] particles being substantially larger than said microparticles and being water-soluble."

31. The '910 patent states that it is an improvement upon the prior art ordered mixture as described in Nystrom and it specifically points out Nystrom as disclosing the preferred method for "formulating rapidly dissolving ordered-mixture compositions," column 3, lines 26-30. There are two obvious differences between Nystrom and the '910 patent. First, the '910 patent involves sublingual tablets and Nystrom does not mention sublingual tablets. Second, and

maybe more importantly for present purposes, the '910 patent describes and claims the use of a bio/mucoadhesive specifically on the surface of the carrier particles.

32. The hygroscopic properties of the bio/mucoadhesive agents described in the '910 patent requires that the formulation is essentially water free as discussed at column 7, lines 40-43:

> Irrespective of the form given to the preparation, it is important that the preparation is essentially free from water, since its bio/mucoadhesion promoting character results from its practically instantaneous hydration when brought into contact with water or saliva. Premature hydration would drastically decrease the mucoadhesion promoting properties and result in a premature dissolution of the active substance.

33. As noted above, the '910 patent states the "bio/mucoadhesion promoting character results from its practically instantaneous hydration when brought into contact with water or saliva." Additionally, "[p]remature hydration would drastically decrease the mucoadhesion promoting properties." Water exposure affects the mucoadhesive properties by causing the bio/mucoadhesive agent to swell slightly which could further disrupt adjacent particles resulting in a change in the overall order of the compositions. In addition, the premature addition of water will also affect the water soluble carrier particle and will likely make it such that the bio/mucoadhesive is no longer "adhered to the surface" of the carrier particle. If part of the carrier particle dissolves prematurely, any bio/mucoadhesive particles that were adhered to the now-dissolved carrier particle will obviously no longer be adhered because the bio/mucoadhesive cannot be adhered to what is effectively a liquid.

34. The pharmaceutical composition in the '910 patent must be essentially water free, with no water added during the process.

35. The '910 patent defines the term bio/mucoadhesion promoting agent as a substance that "is effective in making the active agent or agents adhere to the oral mucosa." '910 patent, col. 3, lines 57-59.

36. Bio/mucoadhesive promoting agents are typically water-swellable polymers that adhere to mucous membranes. Upon contact with saliva or mucous secretions in the GI tract, the polymer interacts on a molecular level with macromolecules in the mucous, such as mucin.

V. OVERVIEW OF THE '910 PATENT PROSECUTION HISTORY

37. In my opinion, during the prosecution of the '910 patent, the applicants clearly indicated to the patent office that cross-linked polyvinylpyrrolidone was *not* a "bioadhesion and/or mucoadhesion promoting agent."

38. In the first office action, the examiner rejected all of the relevant claims over Nystrom. Claim 7, as originally submitted, included microcrystalline cellulose in the list of possible bio/mucoadhesives; however, Claim 7 in the issued patent does not include microcrystalline cellulose. Claim 14, as originally submitted is identical to Claim 7 in the issued patent, both included cross-linked polyvinylpyrrolidone in the list of disintegrating agents.

39. The examiner explained the first office action rejection by noting that "Nystrom teaches essential elements of the claimed invention. The reference discloses an ordered mixture of drug particles in a carrier composition." (ORM_00000159). The examiner further noted:

> With regard to the constituents of the present invention, specifically the carrier particles, these are also well known in the art. *Nyström clearly names the bio/mucoadhesive (microcrystalline cellulose), the disintegrant (polyvinylpyrrolidone) and the carbohydrate (mannitol) of the current invention...*

(Sept. 26, 2002 Office Action, p. 6 (ORM_00000161)) (emphasis added).

40. I note, that in the Office Action, the examiner referred to "polyvinylpyrrolidone" rather than "cross-linked polyvinylpyrrolidone." When I read this statement, I understood that the examiner to be referring to the cross-linked version of polyvinylpyrrolidone. The basis for this conclusion follows.

41. Cross-linked polyvinylpyrrolidone (also referred to as crospovidone) is a common pharmaceutical excipient classified as a "disintegrant" or "disintegrating agent." Crospovidone is used in pharmaceutical formulations to help break up tablets or capsule contents once they are

swallowed. It performs this disintegrating function by absorbing water, which causes the polymeric particles to swell. This swelling action causes tablets or capsule contents containing the disintegrant to break apart.

42. The functionality of cross-linked polyvinylpyrrolidone is directly contradictory to polyvinylpyrrolidone, another pharmaceutically acceptable ingredient commonly referred to as povidone or PVP. As the name clearly states, cross-linked polyvinylpyrrolidone is a cross-linked derivative of PVP. While the two compounds contain the same base molecule, their pharmaceutical properties are essentially opposite. When PVP is put into contact with water, it becomes sticky and tacky. For this reason, it is often referred to as a "binder." The function of PVP in a pharmaceutical formulation is to hold other ingredients together during processing of powders into granules for encapsulation or tableting. Once the water is removed through a drying step, the PVP remains as a strong adhesive to keep particles together as granules. I have used PVP throughout my 27 year career in formulation development, and in that time, I have used PVP in tablet and capsule formulations as a binder. I have never used PVP as a disintegrant, and, I have never known any formulators to have used PVP, in its non-cross-linked form, as a disintegrant.

43. In response to the office action rejection of all claims, the applicants amended the specification and the claims to remove microcrystalline cellulose from their definition of bio/mucoadhesives. The applicants, however, then also took additional steps. Following some preliminary arguments, the applicants pointed to the change in the patent specification in their effort to convince the examiner to withdraw his obviousness rejection:

> ***Moreover, applicants note the NYSTROM fails to mention muco- or bioadhesive components. In fact, NYSTROM fails to disclose or suggest a combination of ordered mixtures and mucoadhesive agents.*** Moreover, applicants note that one of the ordinary skill in the art would appreciate that microcrystalline cellulose does not exhibit bio/mucoadhesive properties. While it is true that this is stated in the specification and claims, applicants have amended the claims and specification to correct this obvious error.

(Feb. 23, 2003 Amendment, p. 6 (ORM_00000181) (emphasis added).)

44. I have reviewed the Nystrom reference, and it discloses cross-linked polyvinylpyrrolidone as a "disintegrant" at column 3, lines 8-18 (emphasis added):

> The ***pharmaceutical disintegrant*** may comprise any substance which is known for this purpose by those skilled in the art. Particularly effective agents in this respect are those which swell drastically in water, through hydratization, and thus exhibit an increase in volume of up to 10-20 times their dry volume. Examples of such agents are cellulose and starch derivatives in the form of water-insoluble, cross-linked polymers which swell markedly in water. ***Derivatives of polyvinylpyrrolidone*** are other examples of such agents.

45. The only "[d]erivative[] of polyvinylpyrrolidone" of which I am aware is known as a "pharmaceutical disintegrant" is cross-linked polyvinylpyrrolidone. When I read this section in Nystrom, I read it as disclosing cross-linked polyvinylpyrrolidone and its use as a disintegrating agent. In my opinion, any formulation scientist would come to the same conclusion.

46. Nystrom also disclosed the combination of ordered mixtures and *disintegrants.* *See* Nystrom at col. 5, lines 5-14:

> The pharmaceutical preparations can be composed, by ***combining the inventive ordered mixtures with*** the conventional pharmaceutical additives and excipients normally used in the desired forms of the preparations, with the aid of known methods herefor. Such additions may comprise, for instance, additional carriers, preservatives, lubricants, glidants, ***disintegrants***, flavourants, dyestuffs and like substances, and are well known to the person skilled in the art. (emphasis added).

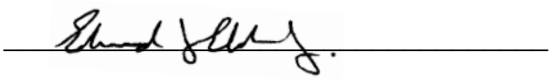
47. Reading the statements in the preceding paragraphs and combining the three key points: 1) noting that the Nystrom reference "fails to mention muco- or bioadhesive components" and that it fails to "disclose or suggest a combination of ordered mixtures and mucoadhesive agents" (¶ 43), 2) the Nystrom reference disclosing cross-linked polyvinylpyrrolidone (¶¶ 44-45) and 3) the Nystrom reference disclosing the use of disintegrants (i.e., cross-linked polyvinylpyrrolidone) with an ordered mixture (¶ 46), I understand these statements to say that

cross-linked polyvinylpyrrolidone was not a bio/mucoadhesion agent for purposes of the '910 patent.

48. I read these statements to allow the use of both microcrystalline cellulose and cross-linked polyvinylpyrrolidone in a pharmaceutical formulation because neither are bio/mucoadhesives for purposes of the '910 patent.

I, EDMUND J. ELDER, JR., hereby declare under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

Dated: October 5, 2012



Edmund J. Elder, Jr.

EXHIBIT A

Edmund J. Elder, Jr., Ph.D., R.Ph.
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University of Wisconsin-Madison
School of Pharmacy
Rennebohm Hall
777 Highland Avenue
Madison, WI 53705-2222
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EDUCATION:

Medical University of South Carolina, Charleston, SC
Ph. D., Pharmaceutical Sciences; November 1989
B.S., Pharmacy; May 1985

Clemson University, Clemson, SC
Pre-Professional Studies, Pre-Pharmacy
1980-1982

EMPLOYMENT:

University of Wisconsin-Madison
School of Pharmacy
Director, Lenor Zeeh Pharmaceutical Experiment Station, July 2007 – present
Associate Director, Lenor Zeeh Pharmaceutical Experiment Station, April 2006 – June 2007

Current Responsibilities
- Key leadership position for providing laboratory services to UW and non-UW clients, including analytical, physical/chemical characterization (pre-formulation), and early-stage formulation services
- Provide pharmaceutics expertise and chemistry, manufacturing and controls (CMC) knowledge to support pharmaceutical and biopharmaceutical development collaborations on and off campus
- Advise and mentor Station staff
- Apply project management and business development experience to enhance Station operational effectiveness
- Share knowledge and expertise through Station participation in and sponsorship of educational programs addressing the process and science of drug development in collaboration with UW-Madison, School of Pharmacy, Extension Services in Pharmacy (continuing education division)
- Graduate Course Lectures:
  - An Introduction to Pharmaceutical Sciences
  - Approaches to Formulation of Drug Products

The Dow Chemical Company, Midland MI
Dowpharma[SM]
Global Pharmaceutical Development Director / Applications Development Leader, April 2004 – April 2006
Pharmaceutical Technologies Group
Pharmaceutics Director / Technical Leader, August 2000 – April 2004

Prior Responsibilities
- Co-leader (with commercial leader), new business development: BioAqueous[SM] Solubilization Services
- Oversight of multi-departmental technical activities for development of a drug delivery service offering including interfacial sciences, engineering, analytical, toxicology, intellectual capital management, licensing, manufacturing, project management, technical service and QA/regulatory
- Lead external technology development collaborations and alliances including a multi-year university research program
- Represent technical program during client interactions for commercial development activities
- Provide pharmaceutics expertise for various emerging corporate growth opportunities
- Serve as a mentor for potential future leadership staff through formal corporate program

[SM] Service Mark of The Dow Chemical Company

Glaxo / Glaxo Wellcome (now GlaxoSmithKline), Research Triangle Park, NC
Pharmaceutical Sciences
Sr. Group Leader, Formulation and Process Development, November 1997 – August 2000
Group Leader, Formulation Development, February 1997 – November 1997
Process Science and Technology
Research Leader, Liquids Process Development, September 1995 – February 1997
Research Leader, Pharmaceutical Technology Development, July 1994 – August 1995
Research Investigator, May 1992 – June 1994
Senior Scientist, September 1989 – April 1992

Previous Experience

- Management: Group of ten formulation and process development scientists, covering all dosage forms, mentoring of new CMC team leaders, department management team and division leadership committees
- Project Management: Chemistry manufacturing & controls (CMC) matrix team leader
  - Responsible for oversight of all cross-functional CMC activities for multiple development programs
  - Represented CMC interests on international product development teams
  - Lead technology transfer and manufacturing site new product implementation teams.
  - Key R&D contact for FDA pre-approval inspections of domestic and foreign contract manufacturing sites.
- Formulation and process development, optimization and scale-up using statistical experimental design
- Primary interface with external development and manufacturing sites for new dosage form technologies including: soft gelatin capsules, effervescent products, and sterile products blow-fill-seal technology

Burroughs Wellcome Company (now GlaxoSmithKline), Greenville, NC
Pharmaceutical Research and Development Laboratory
Pharmaceutics Graduate Student Fellow, June 1986 – August 1986

Family Pharmaceuticals of America, Inc., Mt. Pleasant, SC
Mail-service and retail pharmacy, acquired by Medi-Mail, Inc. in 1994, subsequently acquired by Bergen Brunswig Corporation, now AmerisourceBergen Corporation
Minor Partner, subchapter-S corporation, January 1987 – June 1994
Part-time Pharmacist, June 1985 – August 1989
Pharmacy Intern, May 1983 – June 1985

PROFESSIONAL ACHIEVEMENTS:

52 Scientific Presentations (15 invited)

9 Publications and 1 book contribution

112 Short Course presentations (all invited), additional 17 presented at pharmaceutical companies

The Visiting Scientist Program for Schools of Pharmacy and Pharmaceutical Scientists
- Presented lectures/seminars at 14 schools/colleges of Pharmacy, 1993 – 2005

Guest Lecturer
- University of Wisconsin–Madison, Department of Pharmaceutical Sciences, 2006 – present
- South Carolina College of Pharmacy, MUSC Campus, 2007
- Medical University of South Carolina, Department of Pharmaceutical Sciences, 1991 – 1999
- University of Texas at Austin, College of Pharmacy, 2001 – 2006
- Michigan State University, ISPE Student Chapter, 2004
- Virginia Commonwealth University/Medical College of Virginia, School of Pharmacy, 1997

LICENSURE:

South Carolina Pharmacist License, 1985 – present
Wisconsin Pharmacist License, 2010 – present

PROFESSIONAL MEMBERSHIP/ACTIVITIES/AWARDS

United States Pharmacopoeia (USP)
- 2010-2015 Compounding Expert Committee

American Association of Pharmaceutical Scientists (AAPS), 1990–present (student member 1987–1989)
- Annual Meeting paper screener (PT Section), 1994 – 2000, 2006 – 2009, (FDD Section) 2011
- Co-Chair 2004 Annual Meeting Short Course, Particle Engineering Technologies: Theory and Practice
- Moderator (PT Podium Session: *Pharmaceutical Processing and Scale-up*), Tenth Annual Meeting and Exposition, Miami Beach, FL, 1995
- Planning Committee and Moderator (PT Section), 1995 Southeast Regional Meeting, RTP, NC
- AAPS Special Appreciation Award, 1994 – Co-Chair, 1994 Southeast Regional Meeting, Durham, NC

Controlled Release Society (CRS), member 2001 – 2006

European Federation for Pharmaceutical Sciences (EUFEPS), member 2003–2008, 2009 – present

Sigma Xi, The Scientific Research Society, member 1988 – present

Editorial Advisory Board
- *Drug Development and Industrial Pharmacy*, 2006 – present
- *Journal of Biosimilars & Biowaivers,* 2012 – present

Journal Article Reviewer
- *Drug Development and Industrial Pharmacy*, 2000 – present
- *European Journal of Pharmaceutics and Biopharmaceutics*, 2007, 2010, 2011
- *International Journal of Pharmaceutics,* 2007, 2009, 2010
- *Journal of Biomedical Nanotechnology* – Special Issue on “Nanotechnology in Advanced Drug Delivery”, 2006
- *Journal of Drug Delivery Science & Technology*, 2008
- *Journal of Pharmacy & Pharmacology,* 2009, 2011
- *Pharmaceutical Research*, 2008

Grant Reviewer
- National Science Foundation, Office of Industrial Innovation, Small Business Innovation Research/Technology Transfer, SBIR/STTR Phase I, Food Safety, Drug, and Nutraceutical Manufacturing Panel, 2006
- University of Minnesota, Center for Nanostructure Applications, 2007, 2008

University of Wisconsin–Madison, Extension Services in Pharmacy, Pharmaceutical Industry Courses
- Applied Drug Development I (introduction) Short Course, 2008-2010
- Applied Drug Development II (pre-formulation) Short Course, 2007-present
- Applied Drug Development III (formulation) Short Course, 2008-present
- CMC Project Team Leader Short Course, 2010-present
- Land O’Lakes June R&D Conference, planning committee 2008-present, chair 2013
- Nanoparticles Short Course, 2007-2008

Medical University of South Carolina (MUSC), *Lifetime Member, MUSC Alumni Association*
- Alumni Association Planning Committee, College of Pharmacy, Class of 1985, Reunion 2000
- Chairman, College of Graduate Studies Annual Fund, 1998 – 1999
- Alumni Association Student Research Day Judge, 1996 – 1998
- The Rho Chi Society (Pharmacy Honorary), College of Pharmacy, 1987
- Roche Pharmacy Communications Award, College of Pharmacy, 1985
- McKesson Presidential Award, College of Pharmacy, 1985

ISPE Award for Outstanding Service to the Technology Transfer Task Team, November 2003 (book contributions)

The Dow Chemical Company, Special Recognition Award, December 2002 (creation and launch of BioAqueous^{SM} Solubilization Services)

Boy Scouts of America
- Troop 628 Madison, WI
  - Advancement Chair, 2012 – Present
  - Troop Committee Secretary, 2010 – 2012
- Cubmaster, Pack 628 Madison, WI, 2008 – 2010
- Eagle Scout, Troop 1429 Charleroi, PA, July 26, 1976, *Life Member, National Eagle Scout Association*

PUBLICATIONS

LT Schulz, **EJ Elder**, KJ Jones, A Vijayan, BD Johnson, JE Meadow, LC Vermulen (2010) Stability of Sodium Nitroprusside and Sodium Thiosulfate 1:10 Intravenous Admixture, *Hospital Pharmacy*, 45(10): 779-784, **2010**.

ME Matteucci, BK Brettmann, TL Rogers, **EJ Elder**, RO Williams III, and KP Johnston, Design of Potent Amorphous Drug Nanoparticles for Rapid Generation of Highly Supersaturated Media, *Molecular Pharmaceutics*, 4(5): 782-793, **2007**.

EJ Elder, JC Evans, BD Scherzer, JE Hitt, GB Kupperblatt, SA Saghir, and DA Markham, Preparation, Characterization, and Scale-up of Ketoconazole with Enhanced Dissolution and Bioavailability, *Drug Development and Industrial Pharmacy*, 33:7, 755 - 765, **2007**.

EJ Elder, JE Hitt, TL Rogers, CJ Tucker, SA Saghir, S Svenson, and JC Evans, Particle Engineering of Poorly Water Soluble Drugs by Controlled Precipitation in Polymeric Drug Delivery Volume II - Polymeric Matrices and Drug Particle Engineering, Svenson, S., (Ed.), ACS Symposium Series, Vol. 924, American Chemical Society, Washington, DC, **2006**.

JC Evans, BD Scherzer, CD Tocco, GB Kupperblatt, JN Becker, DL Wilson, SA Saghir, and **EJ Elder**, Preparation of Nanostructured Particles of Poorly Water Soluble Drugs via a Novel Ultra-Rapid Freezing Technology in Polymeric Drug Delivery Volume II - Polymeric Matrices and Drug Particle Engineering, Svenson, S., (Ed.), ACS Symposium Series, Vol. 924, American Chemical Society, Washington, DC, **2006**.

TL Rogers, IB Gillespie, JE Hitt, KL Fransen, CA Crowl, CJ Tucker, GB Kupperblatt, JN Becker, DL Wilson, C Todd, CF Broomall, JC Evans, and **EJ Elder**, Development and Characterization of a Scalable Controlled Precipitation Process to Enhance the Dissolution of Poorly Water-Soluble Drugs, *Pharmaceutical Research*, 21(11), 2048-2057, **2004**.

RD Connors and **EJ Elder**, Using a Portfolio of Particle Growth Technologies to Enable Delivery of Drugs With Poor Water Solubility, *Drug Delivery Technology*, 4(8), 78-83, **2004**.

EJ Elder, JE Hitt, TL Rogers, CJ Tucker, SA Saghir, S Svenson, and JC Evans, Particle Engineering of Poorly Water Soluble Drugs by Controlled Precipitation, *Polymeric Materials Science and Engineering*, 89:741, **2003**.

JC Evans, BD Scherzer, CD Tocco, GB Kupperblatt, JN Becker, DL Wilson, SA Saghir, and **EJ Elder**, Preparation of nanostructured particles of poorly water soluble drugs via a novel ultra-rapid freezing technology, *Polymeric Materials Science and Engineering*, 89:742, **2003**.

BOOK CONTRIBUTIONS

EJ Elder (contributor), Dosage Forms (Clinical Supplies and Commercial Product): APIs, Excipients and Raw Materials, Chapter 5.3 in Technology Transfer (ISPE Good Practice Guide), ISPE, Tampa, FL, **2003**.

DOCTORAL DISSERTATION

EJ Elder, Development of a Dry Coating Method for Formulating Sustained-Release Products, Medical University of South Carolina, Charleston, SC, **1989**

EXHIBIT B

CONSULTING ACTIVITIES

Testimony by deposition:

1. February 2008
05-cv-340 (KAJ) IN RE Tricor **Direct Purchaser** Antitrust Litigation
United States District Court for the District of Delaware
On behalf of plaintiff, Louisiana Wholesale Drug Company Inc

2. August 2009
Interference No. 105,685; Jerussi et al. (Sepracor Inc.) v. **Hadfield et al. (Wyeth)**
United States Patent and Trademark Office
On behalf of Wyeth

3. February 2010
09-cv-831 (KSH) Endo Pharmaceuticals Inc. et al v. **Impax Laboratories Inc.**
09-cv-836 (KSH) Endo Pharmaceuticals Inc. et al v. **Sandoz Inc.**
09-cv-838 (KSH) Endo Pharmaceuticals Inc. et al v. **Barr Laboratories Inc.**
United States District Court for the District of New Jersey
On behalf of defendants, Impax, Sandoz & Barr

4. March 2010
08-cv-453 (GMS) AstraZeneca LP et al v. **Mylan Pharmaceuticals Inc.**
United States District Court for the District of Delaware
On behalf of defendant, Mylan Pharmaceuticals Inc

5. September 2011
10-cv-4008 (FLW) Medeva Pharma Suisse AG et al v. **Par Pharmaceuticals Inc** et al
United States District Court for the District of New Jersey
On behalf of defendant, Par Pharmaceuticals Inc

6. October 2011
08-cv-6304 (WJM) WARNER CHILCOTT LABORATORIES IRELAND LIMITED et al v. IMPAX LABORATORIES, INC. **et al (Mylan)**
United States District Court for the District of New Jersey
On behalf of defendant, Mylan Pharmaceuticals Inc

7. March 2012
T-2010-10 (Canada) AstraZeneca Canada Inc et al v. **Ranbaxy Pharmaceuticals Canada Inc** et al
Federal Court [Canada] Toronto
On behalf of defendant, Ranbaxy Pharmaceuticals Canada Inc

Testimony at Trial:
1. May 2010
08-cv-453 (GMS) AstraZeneca LP et al v. **Mylan Pharmaceuticals Inc.**
United States District Court for the District of Delaware
On behalf of defendant, Mylan Pharmaceuticals Inc

2. February 2012
08-cv-6304 (WJM) WARNER CHILCOTT LABORATORIES IRELAND LIMITED et al v. IMPAX LABORATORIES, INC. **et al (Mylan)**
United States District Court for the District of New Jersey
On behalf of defendant, Mylan Pharmaceuticals Inc